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The Art and Science of Genetic Modification: Re-Engineering Patent Law and Constitutional Orthodoxies (The Harry T. Ice Chair Inaugural Lecture)

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The Art and Science of Genetic Modification: Re-Engineering Patent Law and Constitutional Orthodoxies

YVONNE CRIPPS*

INTRODUCTION

I am delighted and honored to inaugurate the Harry T. Ice Chair of Law and to have this opportunity to thank my colleagues for their wonderfully warm welcome to Bloomington. They have created a supremely stimulating and collegial environment in the Law School and have done so much to include me in all aspects of this outstanding community. I am extremely grateful to them and to the Ice Miller partnership for the immense privilege of being the holder of the Chair endowed by the partnership in honor of the great Harry T. Ice.

After graduating from Harvard Law School in 1929, Harry T. Ice joined a firm then known as Matson Carter Ross & McCord. At that time, the firm consisted of a small group of talented lawyers; by the time of Harry's death in 1982 it had, under his inspired leadership and guidance, grown into a firm of ninety lawyers with an outstanding national reputation. It has been a particular pleasure to meet Harry's family today and to share their joy at this occasion in his honor.

Shortly after I arrived in Bloomington, Bill Riggs, one of the senior partners of Ice Miller, very kindly gave me a book written by Harry T. Ice about the firm.¹ Reading it reinforced my sadness at never having met Harry. Despite his considerable modesty about his achievements, he was clearly a pivotal member of the partnership, inspiring his colleagues through his own example and his love for the firm as a group of individuals engaged in a common purpose. The book whetted my appetite to know more about the man himself, so with the help of Colleen

* This is the text of a lecture inaugurating the Harry T. Ice Chair of Law at the Indiana University School of Law in Bloomington. The lecture was delivered in February 2002. Although some later inclusions have been possible, the law is stated at that date. I would like to express deep thanks to my research assistants, Christopher Humphreys and Jeffrey Ankrom, and my colleagues Dawn Johnsen (Indiana University) and Elisabeth Zoller (University of Paris) for their excellent advice on some of the more difficult issues raised by this subject.

1. HARRY T. ICE, *HISTORY OF A HOOSIER LAW FIRM: ICE MILLER DONADIO & RYAN AND ITS PREDECESSORS 1910–1980* (1980).

Pauwels and her excellent staff in the Law School's Library, I learned more about Harry Ice's unstinting contributions to the life of his firm and wider community. He was, by all accounts, always finding ways to assist others to achieve their goals, both within the firm and in Indianapolis, which was the focal point for his many charitable activities. His willingness to make his time and talents available to the many who would benefit from them is reflected not only in his colleagues' comments but also in the newspaper records of his many civic good works.

I trust that Harry would not have disapproved of my topic today, for all that I have heard and read about him suggests that he would encourage a struggling colleague in the law, and I shall hope for that indulgence from you too. The title of this lecture speaks of *re-engineering* and *modification* because my topic today is genetic engineering, or recombinant DNA technology. This includes cloning because, as we shall see, even cloning involves a small amount of recombination of DNA: clones are not absolutely genetically identical to the organism from which they are cloned.²

It was our own Hoosier, James Watson, who—in collaboration with Francis Crick, and basing his hypotheses on work by Rosalind Franklin³—discovered the magnificent double-helix structure of the DNA molecule. This is one of the many scientific structures that we can admire almost as if they were works of art: there is great beauty in that complex but symmetrical form. Watson and Crick did not patent their discovery. In the 1950s,⁴ it would have been thought both absurd and offensive to patent what would rightly have been regarded as the discovery of a natural element (such as the structure of a molecule or the molecule itself), regardless of whether it was as fundamental to life as this one. A patent grants a limited monopoly right over the subject matter of the patent, as part of a so-called intellectual property, designed to provide incentives for the production of inventions rather than the discovery of natural elements or forces. Although that point has been extremely well established in patent practice and case law, it is an interesting and little noted feature of Article I of the Constitution

2. See, e.g., Taeyoung Shin et al., *A Cat Cloned by Nuclear Transplantation*, 415 NATURE 859 (2002).

3. The role of Rosalind Franklin in this discovery is described in ANNE SAYRE, *ROSALIND FRANKLIN AND DNA* (1975) and BRENDA MADDOX, *ROSALIND FRANKLIN: THE DARK LADY OF DNA* (2002).

4. Nowadays there are attempts to build life using just a few basic chemicals, notably in Craig Venter's Minimal Genome Project. See Nick Campbell, *I Can't Live Without You*, 4 NATURE REVIEWS GENETICS 405 (2003).

that it refers to the power of Congress to secure for inventors rights to their “discoveries,” but the constitutional wording also requires “inventors.”

As a lawyer interested in biotechnology, I find it difficult to restrict myself to any one of the many interconnected areas in which law and biotechnology intersect. Administrative law, constitutional law, criminal law, employment law, environmental law, evidence, family law, insurance law, intellectual property law, the law of succession, and tort law, to name but a few, all impinge on this rapidly developing technology. But since, unlike Dolly the sheep,⁵ we are, for the present, confined to what we think of as our real age and real time, it might be prudent to focus today on one area in particular, knowing that this too will involve inevitable excursions into related areas of law. Thus I am going to concentrate on intellectual property law, and in particular patents, and my emphasis today will be on medical rather than agricultural developments.⁶ Patent law illustrates several of what I perceive to be the most important legal issues arising from biotechnology. While I am attempting not to stray too far from patent law, it is, however, difficult to resist noting in passing that several individuals have paid significant fees to sign up with an organization that has purported to *copyright* their DNA or genetic code in order to protect their intellectual property rights to themselves for the day when others clone them without permission. Such cloning may eventually be possible from a hair removed, for instance, from a coat hanging in a cloakroom. Some potentially fascinating criminal as well as civil law issues arise in that context, not least in relation to theft, misappropriation, and trade dress or passing off, but we must save those for another day. It suffices for the moment to note that, from a website⁷ that appeared in 2001, the DNA Copyright Institute offers services including archiving clients’ genetic data (for use, for example, as evidence in DNA misappropriation actions). The

5. Before Dolly’s birth in July 1996, reports appeared on the technique that had been used. *See, e.g.*, K.H.S. Campbell et al., *Sheep Cloned by Nuclear Transfer from a Cultured Cell Line*, 380 NATURE 64 (1996). The announcement specific to Dolly appeared as I. Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810 (1997).

6. I have discussed agricultural developments elsewhere. *See, e.g.*, Yvonne Cripps, *Aspects of Intellectual Property in Biotechnology: Some European Legal Perspectives*, in PROTECTION OF GLOBAL BIODIVERSITY: CONVERGING STRATEGIES 316 (Lakshman D. Guruswamy & Jeffery A. McNeely eds., 1998). I also discuss agricultural as well as medicinal and human biological issues in Yvonne Cripps, *Patenting Resources: Biotechnology and the Concept of Sustainable Development*, 9 IND. J. GLOBAL LEGAL STUD. 119 (2001) [hereinafter *Patenting Resources*].

7. DNA Copyright Institute, <http://www.dnacopyright.com> (last visited Sept. 24, 2003).

"Institute" makes no claim that the company will register DNA with the Copyright Office of the Library of Congress and no direct claim that such a registration is possible. Nonetheless, it quotes from the Copyright Act and proclaims that "it should be possible for any person to establish a DNA Copyright for themselves [*sic*]."⁸ We are not, however, told how a work is created for this purpose, or when the crucial creation occurs.

We shall also see that litigation over patents on biotechnological inventions can give rise to questions of constitutional law and environmental law, as in the case of the patent on the Harvard mouse, which has been tested on constitutional grounds by the Supreme Court of Canada,⁹ and on environmental grounds by the European Patent Office.¹⁰ The mouse was genetically engineered to be particularly susceptible to cancer. We shall return to Harvard and its famous mice shortly.

I. ANNEXING NATURE AND STIFLING INNOVATION

While it is true that many different fields of law impinge upon biotechnology, biotechnology is perhaps the only technology directly to have led to major alterations in patent law and practice.¹¹ I refer here to my belief that the extraordinary nature of biotechnology has altered the ways in which the fundamental, traditional tenets of patent law are applied in that field. These classic tenets require an *invention* that is, among other things, novel, nonobvious, and useful. Belief on the part of governments and patent offices in the power of biotechnology, and therefore in its commercial potential, has in my opinion combined with fear of loss of competitiveness in international markets, to cause the traditional tests or standards for patentability to be dropped to alarmingly low levels, or in some instances ignored in all but name. This trend would be disturbing even if the inventions in question were of a purely mechanical nature, but is of much greater concern where the subject matter of the patent applications is an entire

8. *Id.* at <http://www.dnacopyright.com/copyrightinformation/index.html>.

9. *Comm'r of Patents v. Harvard Coll.*, [2002] 219 D.L.R. (4th) 577 (Can.).

10. European Patent No. 0 169 762 (application published Jan. 29, 1986), *available at* LEXIS EP-B 1696000072. For history and official announcement, see 1992 O.J. EUR. PAT. OFF. 588, *available at* http://www.european-patent-office.org/news/pressrel/pdf/oj1992_10_p588_593.pdf.

11. Semiconductor chip technology and other technologies relating to computing and databases led to alterations in intellectual property law as they emerged, but their impact was largely on copyright law.

living organism or a part of a human being. For example, numerous patents have already been granted over human genes,¹² and in some cases over parts of human genes, even where the functions of those parts (or expressed sequence tags) are unknown. The Patent Office has since indicated that it will be more rigorous in requiring applicants to show functionality in this context, but the standard is still applied loosely, with the patent office allowing the use of automated programs that enable researchers to “guess” the identity and function of a protein encoded by a gene based on the similarity of a fragment to other known genes.¹³ How did human gene sequences of *unknown function* meet patent law’s utility requirement, even if they met the inventive-step requirement and even supposing they were inventions as opposed to discoveries? Arguments based on purification scarcely suffice. And why have the thresholds in the tests for patentability been dropped so low in relation to patents on organisms when, apart from any higher order moral questions, common sense and the pragmatism normally characteristic of patent offices would suggest that patenting what might very crudely be described as the raw materials of biotechnological research and development may well impede rather than encourage inventiveness in this sphere? The major purpose of the Patent Act, mandated by Article I of the Constitution, is to provide an incentive for inventiveness. When patents are granted on genes, human or otherwise, any scientist or team, whether operating in the private or the public sector, is required to pay the patent holder if the gene is used diagnostically, in a therapy, or in a pharmaceutical product.¹⁴

Let us consider just two of several situations where the patenting of a human gene has had extremely undesirable consequences for research and development, for those in need of medical treatment, and ultimately for patent holders.¹⁵ Genes that influence the development of breast cancer have been discovered and patented—these are known as BRCA1 and BRCA2. These genes, in addition to a test to determine whether a woman has the genes, were patented

12. See, e.g., U.S. Patent No. 5,397,696 (issued Mar. 14, 1995), available at <http://patft.uspto.gov/natahtml/srchum.htm>.

13. See Paul Smaglik, *As US Tightens up on ‘Speculative’ Claims*, 403 NATURE 3 (2000).

14. See DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW, CASES AND MATERIALS 722 (2d ed. 2001).

15. For a discussion of the patentability of methods of medical treatment, see MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 119–32 (2d ed. 2003).

by Myriad Genetics.¹⁶ Myriad has charged as much as Can \$4,000 (per test application) to those who wish to administer the test, including hospitals.¹⁷ Many hospitals and other health care providers will not pay such a high fee for a single test, and many individuals cannot afford it, especially if any insurance they may have does not extend to it. The situation is aggravated by the fact that, since the discovery of the genes, testing for their presence involves an extremely simple and cheap procedure. Thus the \$2,680 fee in respect of what many would regard as the discovery of the natural phenomena of genes relating to breast cancer is hard to justify. The European Parliament has led opposition to the patents in Europe,¹⁸ and the Government of British Columbia—arguing that it could not afford to fund the tests—cancelled them in its publicly funded hospitals. The Government of Ontario rebelled by taking the extremely unusual step, especially for a public body, of “ignoring the patent and paying another provider \$800 to test for the gene.”¹⁹ Myriad, perhaps overwhelmed, or at least temporarily cowed, by the adverse reactions to its patents has complained but not taken legal action against what would seem to be an infringement of its patent rights. Its position is weakened by the perception that its patent was granted in relation to what could more properly be viewed as a discovery rather than an invention, and a discovery of a naturally occurring human gene at that. It will also not have received any comfort from the recent decision of the Supreme Court of Canada blocking the patent on the Harvard mouse.²⁰ The Court decided that when the Canadian legislature drafted the Canadian Patent Act (which is in broad terms

16. Myriad was granted U.S. patents for forty-seven mutations of BRCA1 alone. *Myriad Receives Patent for BRCA1 Mutations*, 390 NATURE 546 (1997); see also Kimberly Blanton, *Corporate Takeover Exploiting the US Patent System: A Single Company Has Gained Control over Genetic Research and Testing for Breast Cancer, and Scientists, Doctors, and Patients Have to Play by Its Rules*, BOSTON GLOBE, Feb. 24, 2002, at Magazine 10, available at 2002 WL 4113872.

17. See Declan Butler & Sally Goodman, *French Researchers Take a Stand Against Cancer Gene Patent*, 413 NATURE 95 (2001). Fees to patients have varied, but one report cites \$2,680 as a representative fee in the U.S. in 2001. Gautam Naik, *Myriad Faces New Assaults on Its Gene Patents*, WALL ST. J., Sept. 26, 2002, at D4, available at 2002 WL-WSJ 3407134. See David Akin, *For Science or Money*, GLOBE & MAIL (Toronto), Feb. 5, 2002, at A15, available at www.davidakin.com/clips/sciencemoney.html.

18. See, e.g., *European Parliament Resolution on the Patenting of BRCA1 and BRCA2 ('breast cancer') Genes* (Apr. 10, 2001), available at <http://www.cptech.org/ip/health/biotech/eu-brca.html>; Naik, *supra* note 17 at D4; and *French Institutions Oppose Myriad Genetics's Monopoly on Gene Tests* (Sept. 26, 2002), available at <http://www.gene.ch/genet/2002/Ocu/msg00007.html>.

19. See Akin, *supra* note 17, at A15.

20. Comm'r of Patents, 219 D.L.R. (4th) at 577.

the same as the equivalent legislation in the United States) it did not intend to allow the grant of patents on higher organisms. That decision is particularly striking because patents on the Harvard mouse have been widely accepted in many jurisdictions and were part of what seemed to have become the wisdom, received ever since the late 1970s,²¹ that organisms that have been intentionally genetically altered by man are in general patentable. One cannot imagine the same Canadian court upholding a patent annexing naturally occurring, unmodified human genes such as BRCA1 and BRCA2. Myriad was very wise not to sue Ontario, though it took that decision even before the Canadian Supreme Court gave its decision on the Harvard mouse. The results of the various European oppositions to Myriad's European patents are still awaited.

The capacity of doctors to diagnose and study the severe illness of hemochromatosis is also being impeded by the patenting of a gene, HFE. (When HFE bears two common mutations, it is a key cause of a dangerous build up of iron in the body, leading to hemochromatosis.) The patent—which extends, *inter alia*, to the gene and a test for the gene—was initially granted to the Mercator corporation in 1998 but has since been sold from company to company, with each company enforcing the patent.²² This is especially regrettable because, although severe, the illness can be treated easily and very inexpensively once diagnosed. The authors of a study published in *Nature*²³ found that approximately one third of the laboratories that they contacted in the United States had either stopped carrying out tests for the HFE mutation or had never introduced them because of the restrictions imposed by the holders of the patent on the HFE gene. Thus further work on the gene is being impeded, defeating the central purpose of the patent system, which is to facilitate understanding and encourage inventiveness by making available information that can lead to innovation. Here the effect in practical terms is the opposite, as scientists' hands are tied by a patent on the fundamental organic matter upon which they might base developments. And the so-called *experimental use exception*, as currently narrowly interpreted and applied, is of very little assistance.²⁴

21. The world's first patent on a genetically engineered organism was granted to General Electric in relation to a genetically engineered single-celled *Pseudomonas* bacterium invented by Ananda M. Chakrabarty. See U.K. Patent No. 1,436,573 (issued May 19, 1976).

22. See Jon F. Merz et al., *Diagnostic Testing Fails the Test: The Pitfalls of Patents Are Illustrated by the Case of Haemochromatosis*, 415 NATURE 577–78 (2002).

23. *Id.*

24. See Mark D. Janis, *Sustainable Agriculture, Patent Rights, and Plant Innovation*, 9 IND. J. GLOBAL LEGAL STUD. 91, 105–17 (2001).

In more conventional situations, the initial patent grant can be justified by the inventiveness of the original patent applicant, but it is difficult to regard an unmodified human gene as a product of man rather than a product of nature. I stress the word "unmodified" because, in 1980, the Supreme Court of the United States in the *Chakrabarty* case²⁵ decided that the world's first genetically engineered organism was patentable. That organism, a single-celled bacterium, had been genetically manipulated by human intervention into an organism not thought to be found in nature; thus the Supreme Court was able to decide that the patent application in relation to the engineered bacterium was for a product of man rather than a product of nature, within the usual criteria of patent law. The patents on human genes have not yet been tested before the Supreme Court but it is in my view much more difficult to argue that an *unmodified* gene is a product of man. The examples of patents on human genes to which I have specifically referred relate to genes of known function. The most surprising patents of all, in terms of the classic prerequisites for patentability, are those on unmodified nucleotide sequences of human genes where the function of the sequences is not known.²⁶ We have already touched upon the point that it is a fundamental tenet of patent law that a patent will be granted only on an invention which is, among other things, useful.

As if all these inroads into orthodox patent law were not sufficiently disturbing, there has also been a marked tendency in the biotechnological field to grant patents that are overbroad—in other words, where the applicant for a patent claims more than is fully disclosed or demonstrated by the patent specification. Those seeking patents have an interest in encompassing as much as possible within the limited monopoly that a patent confers. Patent law, prior to the age of recombinant DNA research, could generally be relied upon to control overbroad claims by virtue of the fear that if a claim was overbroad the patent application would fail, not least for insufficient disclosure. Indeed the art of drafting a patent claim so that it is neither too broad nor unnecessarily narrow is extremely difficult and rightly highly valued. In the biotechnological field, however, some startlingly overbroad patents have been granted. The patenting of the polymerase chain reaction (PCR) and an overbroad claim to virtually any appli-

25. *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980).

26. *See, e.g.*, U.S. Patent No. 5,397,696, *supra* note 12.

cation of it²⁷ should have served as a warning. The PCR is a biochemical reaction that most genetic engineers will need to use. At least that patent relates to a process rather than a product, but even in the sphere of biotechnological *product* patents some extremely broad claims have been granted. An interesting example of this occurred with the patents on the clone Dolly, our now faded superstar sheep. Indeed, in what was a very bad fortnight for sheep clones, both Dolly and her Australian counterpart Matilda died.²⁸

Although in her patented form Dolly was a Scottish invention, we New Zealanders will admit to an affinity with these shy but not unfriendly creatures that outnumber New Zealand humans in their own country by twenty to one. I refer to sheep as shy, but Dolly the clone became so used to human contact from her earliest days that like a true star, and quite unlike sheep less used to the lime-light, she actually came forward to meet one, or rather more sadly in the latter days of her premature aging, limped forward. The patents granted on Dolly relate not only to all sheep produced by the "Dolly method" of cloning, to which I shall return in a moment, but also to all nonhuman mammalian animals produced by that method as well as to *human* cell lines produced by that method. Those patents are so broad that they may be argued to extend to the cloning of a human being by the Dolly method.

It is crucial to an understanding of the patents granted on Dolly and other clones to appreciate something of the technique that produced her. (We shall not go into the *trademarks* on Dolly today, not even to dwell upon the substantial likelihood of confusion when it comes to comparing one sheep likeness with another.) Note also that both the process used to clone Dolly and Dolly herself have been patented—that is the product Dolly as well as the process of cloning that created her. Animal clones have been produced since the 1960s,²⁹ but Dolly was remarkable in that she was the first mammal to be cloned from a somatic cell, as

27. See U.S. Patent No. 4,683,195 (issued July 28, 1987); U.S. Patent No. 4,683,202 (issued July 28, 1987).

28. Matilda died unexpectedly on Feb. 1, 2003, and was cremated without extensive post mortem analysis. See Alastair Dalton, *Cloned Sheep Death Mystery*, THE SCOTSMAN, Feb. 8, 2003, available at <http://www.news.scotsman.com/archive.cfm?id=156502003>. Dolly was put down on Feb. 14, 2003. See John Whitfield, *Obituary: Dolly the Sheep*, NATURE SCI. UPDATE/NEWS, Feb. 18, 2003, available at <http://www.nature.com/nsu/030217/030217-6.html>.

29. See, e.g., J.B. Gurdon, *Adult Frogs Derived from the Nuclei of Single Somatic Cells*, 4 DEVELOPMENTAL BIOLOGY 256 (1962).

opposed to a reproductive cell, such as an egg or a sperm cell.³⁰ Unlike a reproductive cell, a somatic cell contains the full complement of a creature's chromosomes. It is a mature differentiated cell that could, for example, be used for cloning from the skin or the liver or the heart of an adult; from a male or a female beyond the fertile reproductive years. This possibility fundamentally alters the reproductive landscape. It involves mammalian cloning from an adult cell rather than a reproductive one. Once the cell taken from the creature being cloned is stimulated to replicate (in the case of the Dolly method, by means of the application of an electrical charge to the mammary-gland cell nucleus in question after it has been encased in a host egg cell),³¹ the resulting embryo can be placed into a surrogate mother's uterus or into the uterus of the creature from which the somatic cell was taken and allowed to gestate in what is then optimistically hoped to be the normal way.

In truth, a vast majority of the clones so produced are extremely abnormal—for example, being very much larger than normal; the oversized fetus endangers the surrogate mother while gestating in a uterus in many cases insufficiently large to contain the clone, which then dies, sometimes after having fatally burst the surrogate mother's uterus.³² Two hundred and seventy-seven failed attempts were required to produce Dolly,³³ and even the misleadingly named Identicat was the one success in 188 attempts to clone her parent. There is also considerable evidence that the clones have the "wrong" genetic age. Dolly and Matilda may have been the age of the creature from which they were cloned *plus* their own chronological age.³⁴

30. Cloning from a somatic cell had, however, previously been achieved with frogs by a different method. *See id.*

31. *See* Jim Gilchrist, *A Sheep of Faith*, THE SCOTSMAN, Feb. 19, 2003, at 2, available at <http://www.news.scotsman.com/archive.cfm?id=208722003>; *see also* Roslin Institute, Edinburgh, at <http://www.roslin.ac.uk/public/cloning.html> (for various documents on nuclear transfer by Dolly's creators).

32. *See* Philip Cohen, *Bad Copies: Do Some Clones Lose Something Vital During their Creating?*, NEW SCIENTIST, Feb. 3, 2001, at 7; *see also* Roslin Institute, Edinburgh, *supra* note 31, at <http://www.roslin.ac.uk/public/cloning.html>.

33. *See* Gilchrist, *supra* note 31.

34. *Id.* There remains some controversy over the issue of advanced aging and the relevance of shortened chromosomes. Contrary evidence on genetic aging—from the length of telomeres (chromosome "caps")—has emerged in research on species other than sheep. *See* Gretchen Vogel, *In Contrast to Dolly, Cloning Resets Telomere Clock in Cattle*, 288 SCIENCE 586 (2000). An added misfortune is that Matilda's body was discovered only after a day in the summer heat. Following an

These, in my opinion, are among the reasons why the National Academy of Sciences was right to say that any attempt to clone a human being by use of the Dolly method would be grossly premature.³⁵ Professor Antinori of Italy is already working on such a project,³⁶ Professor Panos Zavos³⁷ claims to have produced a human embryo by the Dolly method, and the Raelians have announced the birth of what they allege is a human clone produced by the same method.³⁸ If such a clone is born, it will not be the first human clone. It is not widely known that human clones have been produced by in vitro fertilization (IVF) laboratories since the early 1990s by the more conventional method of *embryo splitting*, which also creates clones—whom we might describe as artificially induced identical twins. The clones produced by the Dolly method are also near-identical twins, but the Dolly method is, as we have seen, quite different from embryo splitting; and all the scientific evidence suggests that it is much too unreliable, at least as yet, for use on humans. It is my opinion that, in the current state of knowledge, attempts at human cloning by the Dolly method are extraordinarily reckless. Even the IVF techniques that we tend to take much more for granted as a part of reproductive technology are increasingly being found to be associated with unexpected defects. A Swedish study, recently published in *The Lancet* medical journal,³⁹ is the first large-scale investigation into the risk of

autopsy (which did not reveal the cause of death), Matilda's remains were cremated. See John Whitfield, *Obituary: Dolly the Sheep*, NATURE: SCI. UPDATE, Feb. 18, 2003, available at <http://www.nature.com/nsu/030217/030217-6.html>; see also *Mysterious Death of Cloned Sheep*, DAILY MAIL, Feb. 8, 2003, at 9, available at 2003 WL 7266844.

35. Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, Institute of Medicine, *Scientific and Medical Aspects of Human Reproductive Cloning* (National Academies Press 2002) [hereinafter National Academy of Sciences Report].

36. Severino Antinori, an Italian physician, claimed to have cloned and implanted a human embryo in one of his patients. See Alison Abbot, *Disbelief Greets Claim for Creation of First Human Clone*, 416 NATURE 570 (2002).

37. Antonio Regalado, *Human Embryo Is Cloned, Expert to Say in Paper*, WALL ST. J., Apr. 9, 2003, at D2; available at 2003 WL-WSJ 3964291.

38. The Raelian leader, Raël, founded Clonaid in 1997 and subsequently transferred responsibility to a Raelian bishop, Brigitte Boisselier. According to the firm's website, Clonaid is "the first company offering to clone human beings." Clonaid, at <http://clonaid.com/article.php?1.255> (last visited Nov. 17, 2003). As from mid-2003, they claim to have produced five healthy babies, the first of them being Eve, reportedly born Dec. 26, 2002. *Id.*

39. B. Strömberg et al., *Neurological Sequelae in Children Born After In-Vitro Fertilisation: A Population-Based Study*, 359 LANCET 461 (2002), summarized in *Test-Tube Babies Face Triple Risk of Cerebral Palsy: Study*, Agence Fr.-Presse, Feb. 7, 2002, available at 2002 WL 2335082.

neurological disorders in children born after IVF treatment. It found that such children are three times more likely to have cerebral palsy than those conceived naturally. There are also risks to the mothers who have received hormone treatment to increase egg production as part of the IVF process.⁴⁰

Those risks were not anticipated when IVF techniques were applied to humans, but many of the risks involved in cloning humans are very well understood,⁴¹ hence my earlier comment about the recklessness that would in my opinion necessarily be involved in any attempt to clone a human by the Dolly method, in our present state of knowledge. Yet the technology moves so fast that researchers are beginning to understand some of the problems relating to the age of the clones, and we shall also see that technological developments relating to stem cell cloning are already overtaking the ethical debate and the presidential ban on federal funding for some of that work.

But why all this discussion of different types of cloning when I have promised a lawyer's emphasis on biotechnological patents? Patents depend on the claimed organism being, among other things, novel and not obvious. Especially where the cloning takes place by means of nuclear transfer, as in Dolly's case, there will be a contribution of mitochondrial DNA from the host cell into which the nucleus is transferred. Although mitochondrial DNA, existing as it does outside the nucleus, represents only a tiny proportion of the DNA of a cell, it results in a clone that is not totally genetically identical to the parent. The presence of mitochondrial DNA may thus enable those holding patents on clones to fend off challengers who allege that clones are not novel for the purposes of patent law because they are identical to organisms already in existence (the parents). Another argument favorable to the patentees of clones would be that even if a clone were absolutely genetically identical to the parent, a creature produced by the Dolly method of cloning is novel in the sense that it is by definition different in kind from a parent produced by wholly different means. That argument might be maintained while focusing on the patent on the product as well as the patent on the process. The Identicat and other animal clones have enabled us to realize that there are also subtle changes to genetic material that are caused by environmental and developmen-

40. See, e.g., *Experts Offer Hope of Avoiding Serious Complication of Assisted Reproduction*, WOMEN'S HEALTH WKLY., July 24, 2003, at 58, available at 2003 WL 8993315.

41. Primates (including humans) appear to have genetic peculiarities that may preclude reproductive cloning by the "Dolly technique" (somatic cell nuclear transfer). Gretchen Vogel, *Misguided Chromosomes Foil Primate Cloning*, 300 SCIENCE 225-26 (2003).

tal influences while an embryo is within the uterus. These result in clones that are subtly, and sometimes not so subtly, genetically different from their parent even at the point of birth,⁴² although that raises nice legal questions regarding the developmental stage at which the novelty of the clone *qua* invention is judged. Such legal issues are unique to inventions that are not stable in the same way that a more conventional invention, such as an inorganic machine, is stable, and they are particularly difficult to address where the invention is an organism that can go on to reproduce. There are also fascinating issues regarding the extent to which a patent may confer intellectual property rights on progeny and the constitutional implications if those progeny are human.

Niceties of patent law are already being argued in relation to existing patents on clones. Litigation has, for example, commenced between three companies (Geron, Infigen, and Advanced Cell Technology), each of which is claiming "first to invent" rights to cloning and clones produced by the Dolly method.⁴³ PPL Therapeutics, the corporate arm of Dolly's Roslin Institute, sold its patent rights on her and the technology that produced her to Geron, a corporation based in California. In terms of the monopoly rights involved, it is interesting to note that Geron has secured an exclusive license for significant uses of the stem cell patents from the University of Wisconsin.⁴⁴ But Infigen, a Wisconsin-based corporation argues that it was first with the cloning technology. Although Infigen cloned its first creature, the bovine Gene, six months after Dolly was born, U.S. patent law gives priority to the first to invent, rather than the first to file a patent application. In most other jurisdictions the first to file prevails. To compound the competing claims, a third company, Advanced Cell Technology (ACT), which produced George and Charlie, the cattle clones, is claiming that it was first to file a patent on the key technology of cloning animals that were genetically engineered before they were cloned.

At the heart of the legal battle is whether the Patent Office fully understood the applications made by Geron and Infigen before it granted a cloning patent to ACT and its partner, the University of Massachusetts at Amherst. The court hearings are likely to take years, as each company in turn presents its highly

42. Shin et al., *supra* note 2, at 859.

43. See Nicholas Wapshott, *Americans Fight over Legacy of Dolly the Sheep*, TIMES (London), Feb. 21, 2002, at 17, available at 2002 WL 4183503.

44. Antonio Regalado, *U.S. Awards Grants to Extend Rolls of Stem-Cell Researchers*, WALL ST. J., Apr. 29, 2002, at B6, available at 2002 WL-WSJ 3393121.

complex scientific case. Judges will be asked to unravel the meaning and chronology of twenty different cloning patents held by the three companies. Geron claims that it was the first to develop the cloning process and the first to lay its discovery before the Patent Office, but alleges that confusion on the part of patent clerks prevented it from having its invention properly registered. Infigen also claims that it was the first to invent cloning and that laboratory records will prove its case. With overtones reminiscent of *Little Dorrit*,⁴⁵ it alleges, *inter alia*, that the Patent Office mislaid its claim. ACT's case rests upon its claim to having understood the detail of the method used to clone an animal reliably. It is also worth noting that the disquietingly named Genetic Savings & Clone Corporation of Texas, which produced the Identicat, operated under license from both ACT and Geron.⁴⁶

II. THE ART OF PUBLIC RELATIONS

I refer in my title to the art as well as the science of genetic engineering in reference, in part, to the beauty of the DNA molecule and, in part, to the fact that patent lawyers judge scientific progress by reference to what, in a term of legal art, is known as "the state of the art." But art emerges in different forms, and the naming of the clones and the companies that clone them has become an art form as well as an important aspect of raising venture capital and launching marketing campaigns. Careful thought is given to choosing names that will make the clones seem appealing to the public. Hence Dolly; the Identicat (also known as the Copy cat); and born, by no accident, on Christmas Day, the five little piggies: Noel, Joy, Star, Mary, and Angel⁴⁷ (names which conceal the fact that all clones will be the same sex not only as the parent but as one another). We also have Freddie, Mickey, and a host of appealing others—no Lady Macbeth or Medusa as yet. The little piggies went off to market but, like the genetically engineered Harvard mouse,⁴⁸ did not do very well there, not least because of the

45. Charles Dickens, *A Poor Man's Tale of a Patent*, HOUSEHOLD WORDS, October 19, 1850, available at http://www.classicbookshelf.com/library/charles_dickens/reprinted_pieces/11/.

46. Wapshott, *supra* note 43, at 17.

47. Mark Court, *These Five Little Piggies Lead the Race for the £5bn Organ Transplant Market*, TIMES (London), Jan. 3, 2002, at 1, available at 2002 WL 4170914.

48. The Harvard mouse (also known as the OncoMouse) proved not to be as useful an innovation as anticipated. It was overly susceptible to cancer, making it difficult to draw useful research

unfortunate public relations and market management crisis caused by the coincidence, if it was a coincidence, of the announcement of the piglets' arrival with the publication by a rival corporation of news of Dolly's premature arthritis.⁴⁹ The importance of the art and science of naming may also be demonstrated by Monsanto's now infamous "terminator" technology. Monsanto's "germination control technology," designed to prevent farmers from successfully using saved seed, proved to be a commercial failure and was withdrawn from the market. The seeds doubtless lacked appeal in principle as well as in name, but their marketability was not enhanced when detractors dubbed them "terminator seeds" and that tag persisted.⁵⁰

While focus on public relations and naming may well pay literal dividends for corporations, we must not be diverted from the substance of the so-called organic inventions in relation to which patent rights are sought. If we focus for the moment on physical rather than ethical concerns in relation to animals engineered with a mixture of human and nonhuman animal genes, we find, for example, concerns about the transmission of animal viruses to humans.⁵¹ Cross-species transmission of viruses has been linked with AIDS and SARS, so we have some knowledge of how dangerous it can be. The risks are significant especially when there is manipulation of RNA as well as DNA in transgenic creatures. Herds of pigs have had human genes inserted into their genomes so that the pigs can be used as a source of organs for pig-to-human heart transplants. Scientists hope that organs from such genetically modified pigs will be less likely to trigger rejection in humans, but at the current state of knowledge, it is impossible to screen for all pig viruses that may be present and as yet unidentified.

These concerns are heightened by consideration by the FDA of the marketing, for consumption and other uses, of the meat and dairy products of animal

conclusions from its laboratory use. The Supreme Court of Canada has refused a patent to the Harvard mouse. Comm'r of Patents, 219 D.L.R. (4th), at 577–78.

49. The Roslin Institute released news of Dolly's arthritis on Jan. 4, 2002, just ten days after the piglets' arrival. The Roslin Institute, Edinburgh, *supra* note 31, at <http://www.roslin.ac.uk/news/articles/141.html>. At this point, Roslin had a long-standing association with Geron. *Id.* at <http://www.roslin.ac.uk/news/press/articles/79.html> (Roslin's May 4, 1999 announcement). PPL Therapeutics and the Roslin Institute had originally been part of a single entity, but their cooperation in 1996 and 1997 was already the labor of two enterprises. PPL presents its own history at http://www.ppl-therapeutics.com/who/who_4.html.

50. Ehsan Masood, *Monsanto Set to Back Down over 'Terminator' Gene?*, 396 NATURE 503 (1998).

51. See Nell Boyce, *Down on the Organ Farm*, U.S. NEWS & WORLD REP., June 16, 2003, at 47, available at 2003 WL 2021782.

clones.⁵² This would open the way for a multibillion-dollar cloning industry, providing everything from cloned family pets, specialized meat and dairy products, and organs for transplantation, to animals that have been genetically engineered to produce medicines. This practice is known as “pharming,” and cattle clones have already changed hands for large sums, in anticipation of the sale of their unconventional milk and meat.

I have thus far referred mainly to patents on animal clones, even though the patents when tested in court may be regarded in some jurisdictions as broad enough to cover human clones and cloning. How does patent law deal with the patenting of human clones? We have seen that humans have been cloned in IVF labs by means of embryo splitting,⁵³ even if not yet by the highly risky and technically imperfect Dolly method—and there is also the vexed question of stem cell cloning. On June 9, 1997, President Clinton proposed to Congress legislation that would have banned human reproductive, as opposed to research or therapeutic, cloning. *Reproductive cloning* involves creating a cloned embryo and implanting it into a woman with the goal of creating a child. *Research cloning*, or *therapeutic cloning*, involves the creation of cloned human embryos that are then destroyed by the removal of their stem cells for research or therapeutic purposes.⁵⁴ The terms as currently applied are confusing because reproductive cloning may in some cases be a first step toward therapy. The legislation proposed by President Clinton never came to fruition,⁵⁵ but he had already banned federal funding for human cloning.⁵⁶

52. See Jennifer L. Brown, *Beef Ranchers Await FDA's Call on Cloning*, ST. LOUIS POST-DISPATCH, Jan. 19, 2003, at E2, available at 2003 WL 3549828; Roy Bragg, *The Hoof Race: Companies Are Trying to Develop a Reliable Animal-Cloning Technique That Can Be Mass-Produced, Marketed*, SAN ANTONIO EXPRESS-NEWS, Sept. 2, 2002, at 1A, available at 2002 WL 23795767.

53. See *Patenting Resources*, *supra* note 6, at 124; J. L. Hall et al., *Experimental Cloning of Human Polyploid Embryos Using an Artificial Zona Pellucida*, 60 FERTILITY & STERILITY S1 (1993) (Supp. Oct. 11–14, 1993). *Contra* Nat'l Advisory Board on Ethics in Reproduction, *Report on Human Cloning Through Embryo Splitting: An Amber Light*, 4 KENNEDY INST. ETHICS J. 251 (1994).

54. See Remarks on Human Cloning Legislation, 38 WEEKLY COMP. PRES. DOC. 571, 608 (Apr. 15, 2002), available at <http://www.whitehouse.gov/news/releases/2002/04/20020410-4.html>.

55. See Human Cloning Prohibition Act, S. 1601, 105th Cong. (1998); see also Press Release, The Executive Office of the President of the U.S.: Office of Mgmt and Budget, S. 1601 – Human Cloning Prohibition Act (Feb. 9, 1998), at <http://www.whitehouse.gov/omb/legislative/sap/105-2/S1601-s.html>.

56. President Clinton's restrictions on funding human cloning began in December 1994 and were renewed and expanded. See, e.g., Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, PUB. PAPERS (1997) bk. 1, at 233, available at http://grants1.nih.gov/grants/policy/cloning_directive.htm.

President Bush has announced a ban on federal funding for certain types of human stem cell cloning,⁵⁷ but the Senate has so far failed to follow the House⁵⁸ in passing legislation that would ban human cloning. Nor has there been any attempt to restrict the privately funded research and development that is entirely unfettered and proceeding apace. It is very important to appreciate in the context of genetic engineering that the balance over the last twenty years or so has shifted very markedly, with the vast majority of funding for research and development now coming from the private rather than the public sector.

In broad terms, therapeutic cloning may involve producing an embryo from a cell taken from the patient. This embryo, sometimes known as a blastocyst⁵⁹ because it is at a very early stage, is allowed to develop for several days so that stem cells from which derive the specialized cells needed to repair spinal injuries and many other diseases, might be harvested. Critics of therapeutic cloning argue that it is a slippery slope that will inevitably lead to reproductive cloning, with identical copies of human beings being produced to satisfy the vanity of people wealthy enough to pay for the privilege. We have already noted that the first pet clone, a cat, was created recently in the United States.⁶⁰ Critics also suggest that human cloning is unnecessary because of the rapid strides made by scientists in isolating stem cells from adults and inducing them to diversify into many different tissue types. Both methods could in principle produce cells or tissues compatible with the patient, because they would originate from his own cells. But the adult route bypasses the need to create a clone, and raises no ethical dilemmas. Few, however, believe that adult stem cells yet offer clear scientific advantages over embryonic cells and, for the time being, it will probably be necessary to continue working on embryos in order to understand how to manipulate adult stem cells.

President Bush's pronouncement banning federal funding for human cloning covers both reproductive and research or therapeutic cloning. The British

57. Press Release, The White House: Office of the Press Secretary, Fact Sheet: Embryonic Stem Cell Research (August 9, 2001), at <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>; cf. Remarks on Human Cloning Legislation, 38 WEEKLY COMP. PRES. DOC. 571, 608 (Apr. 15, 2002) (speech on President's desire to ban human cloning, except for research conducted on animal and human adult stem cells), available at <http://www.whitehouse.gov/news/releases/2002/04/20020410-4.html>.

58. On February 27, 2003, the U.S. House of Representatives passed a bill that would ban all human cloning. See Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. (2003), available at <http://thomas.loc.gov>.

59. A blastocyst is an embryo that has developed for five to seven days after fertilization.

60. See Shin et al., *supra* note 2.

Parliament has passed legislation to allow therapeutic cloning research while banning reproductive cloning.⁶¹ That position has also been endorsed by a well-argued National Academy of Sciences report.⁶² Even with this important research continuing, it could be years before it is usefully employed in clinics. Scientists will need to learn how to ensure that stem cells become the specialized cells required. And if human cloning proves the only way forward, gaining access to an adequate supply of host human egg cells could be an inhibiting factor unless related technological advances are made.

The EU Directive on the patenting of biotechnological inventions bans the patenting of the human body, at the various stages of its formation and development, as well as processes for cloning human beings,⁶³ but no such express prohibition appears in U.S. patent legislation, although the Patent Office has made relevant policy decisions.⁶⁴ Nor does the U.S. have an express "morality" test in its patent legislation. It is important to remember that patents on the genes of particular tribes and patents on numerous nucleotide sequences or expressed sequence tags (ESTs) of the human genome have already been granted,⁶⁵ and since the grant of the patents on Dolly, which extend to cloned human cell lines, we are no longer in the realm of science fiction.

III. THE THIRTEENTH AMENDMENT

The Thirteenth Amendment may form the basis of future constitutional challenges arising out of the grant of patents on human clones—and here we are thinking of *reproductive* cloning resulting in the birth of a child, rather than *therapeutic* cloning which, as we have seen, destroys a cloned embryo that has not existed for more than a few days in a step toward a therapeutic process. We might envisage a scenario where a person is cloned because of special qualities in his

61. Human Reproductive Cloning Act, 2001, c. 23 (Eng.).

62. National Academy of Sciences Report, *supra* note 35.

63. See Council Directive 98/44/EC, art. 6, 1998 O.J. (L 213) 13.

64. If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. § 101 must be made, indicating that the claimed invention is directed to non-statutory subject matter. U.S. DEPT. OF COMMERCE, UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE 2105 (8th ed. 2001). But, in an age of partly human and partly non-human animal chimeras, what is the broadest reasonable interpretation of . . . a human being? See *Patenting Resources*, *supra* note 6, at 123.

65. See, e.g., U.S. Patent No. 5,397,696 (issued Mar. 14, 1995).

blood. Once the clone is born, the clone might receive payment for samples of his special blood, for example, for use for medical purposes.⁶⁶ A company arguing that it has patent rights over that clone by virtue of a prior patent, might then ask for royalties in respect of the use of the clone's blood, thus in effect claiming a share of the clone's earnings. Or an attempt might be made to require the clone to market its blood, so that the patent is "worked." Might such a situation cause the Supreme Court to decide that the granting of patents on human clones is unconstitutional by virtue of the Thirteenth Amendment's prohibition on slavery—or unconstitutional at least in applications that would allow the patent holder rights as against the born clone? Given past jurisprudence, it is perhaps more likely that the Court would prefer to address these issues as questions of "liberty" under the Fourteenth Amendment, to which we shall return shortly in a slightly different context.

The argument in relation to the Thirteenth Amendment is far from uncomplicated, not least because a patent does not confer ownership of the patented entity, as opposed to a right to exclude others from "making, using, or vending the thing patented, without the permission of the patentee."⁶⁷ And this against a constitutional background which in Article I, Section 8, Clause 8 enables Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." This Clause has been authoritatively interpreted by the Supreme Court in *Graham v. John Deere Co.*,⁶⁸ which, although written nearly forty years ago, might have been directed to exactly the problem we have today. Justice Clark stated:

The clause is both a grant of power and a limitation. . . . [T]he Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit granted thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to

66. Cf. *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479 (Cal., 1990).

67. *Bloomer v. McQuewan*, 55 U.S. (1 How) 539, 549 (1852).

68. 383 U.S. 1, at 5–6 (1966).

restrict free access to materials already available. Innovation, advancement and things which may add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must “promote the Progress of . . . useful Arts.” This is the *standard* [Court’s emphasis] expressed in the Constitution and it may not be ignored.⁶⁹

This interpretation of the extremely broad language of Article I might assist future courts, in compelling circumstances—where alleged patent rights were being used in an attempt to control and profit from the activities of human clones—to decide that the Federal Government should not preside over the grant of patents on viable human clones nor indeed on basic information about the human genome that should be publicly available. “Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.”⁷⁰ In the year 2000, President Clinton and Prime Minister Blair released a joint statement in which they applauded the efforts and good intentions of an international group of publicly funded scientists who published data on the Internet, regarding such human genes as they had sequenced, in a manner that would inevitably block patents on what Clinton and Blair, rightly in my opinion, described as “raw fundamental information about the human DNA sequence and its variants.”⁷¹ Sadly, their patent offices did not follow the spirit of this announcement, and patents continue to be granted on unmodified human gene sequences.

IV. MORALITY TESTS IN PATENT LAW

I mentioned a moment ago that, in addition to an express ban on the patenting of human clones, the European patent system, unlike its American counterpart, has an express morality provision that prohibits the patenting of any invention

69. *Id.* at 6.

70. *Id.*

71. See Declan Butler, *US/UK Statement on Genome Data Prompts Debate on “Free Access,”* 404 NATURE 324 (2000).

that is contrary to morality or public order.⁷² The Harvard mouse initially scurried into difficulties with this provision in the European patent system because of considerations of environmental risk relating to the possible escape of the mice into the environment and the danger that this might result in the spread of their cancer susceptibility genes. The suffering of the animal was also taken into account under the morality provision. A European patent was, however, eventually awarded on the ground that the suffering of the mouse and the possible environmental risks were outweighed by what was perceived at the time as the benefit to mankind of the modified mouse. The Upjohn mouse application, which reached the European Patent Office at almost exactly the same time, failed the morality test because, unlike the mouse genetically engineered for the purpose of use in the search for a cure for cancer, its suffering was not in the final analysis found to be outweighed by a sufficient benefit to man. It was genetically modified so as to be entirely hairless as part of the search for a cure for baldness. Such a warm blooded, hairless creature would suffer, and the European Patent Office refused to conclude that, in moral terms, this suffering was outweighed by what it saw as the merely cosmetic potential of the Upjohn mouse.

In the United States, a *common law* morality test flourished in relation, for example, to gambling machines in the 1800s⁷³ but since then has rather fallen into disuse. The common law test could re-emerge with renewed vigor in this context. It may be provoked into action by applications such as Stuart Newman's, in which a patent was sought on a partly animal, partly human chimera.⁷⁴ Various chimeras have already not just hobbled but veritably sprinted through patent offices. The Newman application was a test patent application that expressly raised the question of what percentage of added or substituted human genes an essentially nonhuman genetically engineered animal would have to have before it would be regarded as human by the U.S. Patent Office.⁷⁵

72. Note that both NAFTA, North American Free Trade Agreement, Dec. 8, 1992, art. 1709(2), 32 I.L.M. 289, 673 and General Agreement on Tariffs and Trade, Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), April 15, 1994, art. 27(2), 33 I.L.M. 1125, 1197 provide that contracting states may exclude from patentability any inventions the exploitation of which would be contrary to the *ordre public* or morality.

73. Early gambling-device cases (*e.g.*, *Nat'l Automatic Device Co. v. Lloyd*, 40 F. 89 (N.D. Ill., 1889)) are discussed in Chisum on Patents at 4.03[1][a].

74. *Patenting Resources*, *supra* note 6, at 126.

75. Note also Stuart Newman and Jeremy Rifkin's "humouse" (human-mouse) chimera patent application. In addition to extensive media coverage, the application was summarized by Rifkin

In a recent conference in this Law School, organized and conceived of by Fred Aman and John Applegate, we considered the topic of sustainable development, and I was moved by some of these recent biotechnological developments to address the question of sustainable development outside its usual agricultural context and in relation to human beings.⁷⁶ I shall not re-examine today issues of the extent to which biotechnology is changing what being "human" actually means in legal and other terms, except perhaps to ask whether and at what percentage of human genes these human/animal chimeras will be humans with human rights under the U.S. Constitution. But perhaps I should just note here that, in art. 6(2), the European Directive on biotechnological inventions⁷⁷ prohibits the patenting of "(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; [and] (c) uses of human embryos for industrial or commercial purposes[.]"⁷⁸ These are all described as contrary to public order or morality. The Directive also provides, in art. 5(1), that "[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions."⁷⁹

A prohibition on patenting inventions or processes, the use of which would be contrary to morality, does not of course prevent the development of such inventions or processes. While a lack of patent protection may discourage expenditure on researching and developing immoral inventions, it will not entirely prevent those activities. Separate legislation would be required for that. And if there is no disclosure through patents, the public and the scientific community will be less well informed about work that might otherwise take place under

on his website. Jeremy Rifkin, *The Humouse Human/Animal Chimera Patent Challenge*, at <http://www.foet.org/chimerapatent.htm> (last visited Sep. 18, 2003). The United States Patent and Trademark Office issued a media advisory that a patent application directed to human/non-human chimeras has recently been discussed in the news media. It is the position of the PTO that inventions directed to human/non-human chimeras could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement. Press Release, United States Patent and Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (April 1, 1998), at <http://www.uspto.gov/web/offices/com/speeches/98-06.htm> (last visited Sept. 18, 2003).

76. See *Patenting Resources*, *supra* note 6, at 123.

77. Council Directive 98/44/EC, *supra* note 63, at 18.

78. *Id.*

79. *Id.*

cover of confidentiality.⁸⁰ It should also be noted that if researchers attempt to protect the fruits of their labor by means of trade secrecy rather than patents, they may escape regulation. Patent offices regard themselves as unqualified to judge questions of morality, and it is not surprising that, like the Court in *Chakrabarty*, they would prefer to leave that role to the legislative branch.

The European Directive on the protection of biotechnological inventions provides that patent protection for an invention cannot be denied on grounds of protecting public order solely because the exploitation of the invention is prohibited by law.⁸¹ This means that patent protection may be provided for inventions that the protecting nation considers in some sense or senses immoral. Moral values can also be protected by separate legislative prohibitions on exploitation. On this view, inventors gain the benefits of patent protection and an incentive to innovate, but governments can still discourage research within their borders by prohibiting exploitation of inventions considered harmful.

V. THE FOURTEENTH AMENDMENT

I have tried to confine myself to patent law issues today, but additional constitutional questions arise in relation to other aspects of biotechnology. Could cloning emerge as so highly valued a reproductive or therapeutic technique that the Supreme Court would overturn a statutory ban on cloning as contrary to Fourteenth Amendment protections of "life, liberty or property?" Will parents, for example, argue that cloning is necessary to save the life of an existing child (in other words, the sibling of an intended clone), and that a statutory ban would be contrary to the liberty of the child to undergo a life-saving medical procedure? Will sick persons argue that a ban on federally funded cloning breaches a right to choose life-saving treatment?

80. See Eugene Russo, *Cow-Human Cell News Raises Ethical Issues*, THE SCIENTIST, Dec. 7, 1998, at 1, available at http://www.the-scientist.com/yr1998/dec/russo_pl_981207.html ("[T]he move into the private sector might be one of the unintended and undesirable consequences of [a] congressional ban. Not only are bioethical concerns more difficult to monitor, but academic and government scientists have limited access to potentially valuable, beneficial research.")

81. See Council Directive 98/44/EC, *supra* note 63, at 18 ("Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.")

In *Roe v. Wade*, the Supreme Court held that the privacy right, which is protected under the Fourteenth Amendment's guarantee of liberty, includes a woman's right to choose to end her pregnancy.⁸² The Court did not fully explore what separates the fundamental right to privacy that was infringed by antiabortion regulation from less fundamental types of privacy and liberty that are not protected by the Due Process Clause. It did, however, give examples of spheres of privacy in which fundamental rights may be found. These include choices regarding "marriage, . . . procreation, . . . contraception, . . . family relationships, . . . and child rearing and education."⁸³ But while the early reproductive choice cases focused on family and marriage, the Court's decisions have made clear that the right is one to personal autonomy, though that too is different from a right to life-saving treatment. A choice concerning medical treatment does not necessarily change the nature of a family, unless the word "family" is viewed extremely broadly, but other aspects of the decision in *Roe*, and the subsequent abortion cases, run counter to that argument. Antiabortion laws have been held to be unconstitutional when they do not allow an exception where the woman's health is at risk.⁸⁴ This suggests that the fundamentality of a woman's right to choose an abortion is based on the woman's right to make choices concerning her own health, in addition to her right to make choices about the nature of her family. The Court directly supported this stance in *Stenberg v. Carhart*,⁸⁵ in which it struck down a prohibition on a particular method of abortion—sometimes called the "partial birth" technique. This technique is safer for the woman than the alternatives. The majority held that the state could not prohibit the safer procedure unless it allowed an exception to preserve the life and health of the woman.

A similar conclusion can also be drawn from the decision in *Washington v. Glucksberg*, in which the Supreme Court ruled upon a statute that made it a crime to assist a suicide. The Court upheld the statute, recognizing that there is no fundamental right to end one's life. A majority of the Court, however, indicated that the case would have been decided differently if it had involved some-

82. *Roe v. Wade*, 410 U.S. at 153.

83. *Id.* at 152–53.

84. See *Planned Parenthood v. Casey*, 505 U.S. 833, 879 (1992) ("We also reaffirm *Roe*'s holding that 'subsequent to viability, the State . . . may, if it chooses, regulate, and even proscribe, abortion except where it is necessary . . . for the preservation of the life or health of the mother.'" (quoting *Roe*, 410 U.S. at 164–65)).

85. 530 U.S. 914, 936–37 (2000).

one who was dying in severe pain and who simply wanted to take enough medication to remove the pain, even if it meant hastening death.⁸⁶ This tends to indicate a sphere of privacy, under the constitutional guarantee of liberty, which includes a person's right to choose to undergo desired medical procedures in certain circumstances. What sets this choice apart from other, nonfundamental spheres of privacy, is the fact that this choice concerns a person's own fate and the treatment of his own body.

In the context of abortion, the Court has held that a law infringes a person's right to choose abortion if it places an undue burden on the choice to have an abortion before viability.⁸⁷ Legislation banning human cloning would place more than an undue burden on the petitioner's choice of medical treatment. It would preclude the choice entirely, possibly infringing a right to undergo life-saving medical treatment. Prior to *Planned Parenthood v. Casey* and *Lawrence v. Texas*,⁸⁸ the Court asked whether the state had a compelling interest to the contrary. In *Casey*, the court created the "undue burden" standard of review, asking whether the governmental restriction on liberty amounted to an undue burden. In *Lawrence* it was not entirely clear what standard was being used. This may have been because the Government's interest could be characterized as a purely moral one that was clearly not sufficient to outweigh the petitioner's right to personal autonomy in the making of life-shaping decisions. Future cases will presumably resolve the question of the appropriate standard for review for Fourteenth Amendment claims of protected liberty, but for now, let us apply the traditional strict-scrutiny analysis.

If legislation banning human cloning would arguably infringe a fundamental right by blocking life-saving treatment, the State would have the burden of asserting a compelling interest to which the legislation was narrowly tailored. First, the State might assert that it is protecting the potential life created by the cloning process. Secondly, the State might assert an interest in precluding the unnatural creation of human life. The first interest is similar to that asserted by states that have sought to outlaw abortion. In the abortion context, the Court has held that the potential life of a fetus outweighs the woman's right to choose abor-

86. Glucksberg, 521 U.S. 702, 737–38 (1997) ("There is no dispute that dying patients . . . can obtain palliative care, even when doing so would hasten their deaths.") (O'Connor, J., concurring).

87. See *Casey*, 505 U.S. at 877.

88. *Id.* at 833; *Lawrence v. Texas*, 123 S. Ct. 2472 (2003).

tion after the point of viability. Viability is defined by the Court as the point at which the fetus, with or without artificial aid, "presumably has the capability of meaningful life outside the mother's womb."⁸⁹ In the era of the new reproductive biotechnologies we might even imagine the fetus gestating in an artificial womb. In the case that we are envisaging, however, the distinction between pre- and post-viability is not entirely helpful. On the one hand, a cloned fetus may be considered viable from the time it is "conceived," because it was created with artificial aid, and techniques may be created to sustain its life until "birth." On the other hand, human material can certainly be cloned in such a way that it would never have the potential of leading a life in any ordinary sense. Presumably, the medical procedure in the case that we are envisaging would involve the latter type of cloning. The State's interest in protecting this particularly attenuated form of life would have difficulty competing with the petitioner's privacy right.

The State's second interest might be harder to pin down. It might relate not to the need to prevent the destruction of life, but rather to an interest in preventing its creation. The State might essentially be asserting an interest in preventing scientists and doctors from playing God. The term "playing God" is sometimes used in relation to doctors, who regularly hold the lives of patients in their hands. In the case envisaged, however, the term takes on new meaning. Medical scientists might actually be said to be creating new life. The technique of cloning can appear quite similar, in the abstract, to the biblical account of the creation of Eve from Adam's rib. The State's argument might in essence be that medical scientists are tampering with forces with which they should not interfere. But is morality per se an adequate government interest? In *Lawrence v. Texas*, the citizen's liberty interest (in private, consensual sexual behavior) outweighed the government's interest in protecting morals, as some might see them. In dissent, Justice Scalia laments that a multitude of state laws on sexual morals will "be called into question by today's decision."⁹⁰

Perhaps the conclusion would be different in the case of cloning where an embryo is deliberately created for the purpose of its destruction for medical use or when another human is born as a result of cloning.

89. *Coulautti v. Franklin*, 439 U.S. 379, 387 (1979), *overruled in part on other grounds by Webster v. Reprod. Health Serv.*, 492 U.S. 490 (1989).

90. 123 S. Ct. at 2490 (Scalia, J., dissenting).

On the other hand, cloning might be seen simply as the next step in the science of directing the growth of human tissue. For centuries, doctors have used techniques to direct the growth of patients' tissues. Wounds have been stitched, and skin removed from one part of the body and grafted to others. These techniques use patients' own tissues to fill in wounds or replace damaged parts. Medical techniques involving cloning are quite similar. The primary difference is that human material is removed from the patient, or another, and grown in a place completely separate from the patient's body. The material may be seen to take on its own identity, separate from the patient. Even where the cloned material is not created as a potential life, the idea that scientists could create a potential life using similar techniques, or indeed create an embryo with a view to its destruction (albeit after only a few days of gestation and arguably for laudable reasons) makes legislators and others uneasy.

An interest in preventing the cloning of human material, where no viable life is created, is, however, a purely moral interest. Of course, this may be said of almost all law but, in the case we are considering, the moral interest arguably conflicts with a constitutionally protected fundamental right to life-saving treatment. The State might find it difficult to present evidence that cloning of human tissue to produce nonviable material (in terms of legal definitions of viability) would be detrimental to society in any way other than that it offends prevailing moral values, and, as in *Lawrence*, this may not amount to a compelling State interest.

Then there are the entirely different constitutional arguments that might be made by or in relation to a human clone who is born and lives to reflect upon the moment. Most of these arguments are extremely unlikely to succeed, but they take us into new legal realms in an examination of the meaning of personhood and questions such as whether human cloning, and the patenting of human clones, might infringe or impinge upon either the personhood of the entity who is cloned, the clone, or both. Since even clones are not genetically identical, such arguments would be extremely difficult to sustain and not just for that reason alone. Another paper beckons on these points and on whether a statutory ban on patenting human clones would infringe a scientist's right to "property" within the meaning of the Fourteenth Amendment.⁹¹ If the scenarios themselves seem

91. The current trend is to interpret Fourteenth Amendment property as not including intellectual property, and when faced with the situations we are considering here, the Court would be likely to adhere ever more firmly to that approach.

unlikely, remember that we already have the production of so-called designer babies whereby IVF techniques and genetic screening are used to create siblings whose cells could cure existing children. In a practice now approved by the English Court of Appeal,⁹² the embryos created by IVF are screened to find one or more that are free from the illness in question and have a blood type matching that of the existing child. The other embryos may be stored or discarded.⁹³

CONCLUSION

It is almost exactly twenty-five years since I first had occasion to speak⁹⁴ and write⁹⁵ about the legal implications of biotechnology. Shortly thereafter, the Supreme Court of the United States addressed the new technology in a case involving the constitutional dimensions of an attempt to claim patent rights over a genetically engineered organism. The Court in *Chakrabarty* deliberated upon the legal and scientific dimensions of a modified micro-organism—a single-celled bacterium. Despite having been subjected by counsel for the Commissioner of Patents to a “gruesome parade of horrors,”⁹⁶ a majority of the justices asserted that Chakrabarty’s engineering of the bacterium had turned it into a patentable invention.

Nearly twenty-five years later, the Supreme Court of Canada has refused to uphold the patent on Harvard’s genetically engineered mouse, drawing a distinction between patents on micro-organisms and those on higher animals. While some of the arguments in the *Chakrabarty* case are very recognizable in the litigation and debate of today, the twenty-first century “parade of horrors”

92. *The Queen v. Human Fertilisation and Embryology Auth.*, 3 All E.R. 257 (C.A. 2003), available at 2003 WL 21047341.

93. In a decision of July 27, 1994, the French Conseil Constitutionnel decided that it would not be unconstitutional, in certain circumstances, to destroy embryos that had been stored for at least five years. This law, formerly L152-8, now L2141-7 in the *Code de Sant Publique*, also provides that a human embryo shall not be conceived or used for commercial or industrial purposes. That part of the law was not challenged. Cons. const., July 27, 1994, 94-343/344, available at <http://www.conseil-constitutionnel.fr>.

94. The speech took place at the 49th annual meeting of the Australian and New Zealand Academy for the Advancement of Science. Extracts from the speech were published as Yvonne Cripps, *Novel Genetic Techniques—Some Legal Issues*, 36 N.Z. SCI. REV. 27 (1979).

95. See generally YVONNE CRIPPS, *CONTROLLING TECHNOLOGY: GENETIC ENGINEERING AND THE LAW* (1980).

96. *Chakrabarty*, 447 U.S. at 314.

is considerably more disquieting, despite our increased familiarity with some of the specters along the way. We must now confront not only engineered micro-organisms, but also, for example, claims over clones, and patents on partly human and partly nonhuman animal chimeras, such as were put to the United States Patent Office in the Newman application. And the Supreme Court may soon have to consider the intricacies of the Thirteenth and Fourteenth Amendments in such contexts in addition to the now familiar arguments regarding Article I, Section 8.

In *Chakrabarty*, the Supreme Court emphasized that it was for Congress to regulate the technology and to ban its unacceptable manifestations as well as attempts to patent them.⁹⁷ By the time the Harvard mouse case reached the Supreme Court of Canada, the justices had had almost a quarter of a century to observe that Congress and the Canadian legislature have shown little sign of willingness to intervene, particularly where such intervention would apply to the private sector, where the vast majority of genetic engineering now takes place.

Largely untrammelled corporate interest in this field has combined with a late twentieth and early twenty-first century tendency to extend the scope and application of intellectual property law, and to distort its traditional tenets to accommodate individuals who seek to annex objects, practices, treatments, and, increasingly, higher organisms, which would previously and properly have been regarded as part of the shared public commons, or indeed of nature itself. We have strayed disadvantageously far from the anti-monopolistic warnings contained in the decision in the *Case of Monopolies*,⁹⁸ with its emphasis on the need to keep sight of the overarching public interest. Perhaps the Canadian Harvard mouse case will come to represent a recent sounding of those distant echoes. Nor have the extending tentacles of intellectual property law been confined to unprecedented overreaching in the patent and biotechnological spheres,⁹⁹ though their elongated grasp is in my opinion most remarkable there.

Intellectual property law was designed to encourage innovation by requiring full disclosure of inventions as society's price for the limited monopoly rights that patents confer on inventors. Knowledge about inventions would thereby be

97. See generally, *id.*

98. See *Darcy v. Alle[i]n*, 77 Eng. Rep. 1260 (K.B. 1602).

99. Copyright terms have been extended and new forms of protection devised, enacted, and judicially sanctioned.

made available to the widest possible audience, and the system of rights would facilitate and encourage further inventiveness. Modern manifestations of this branch of law, particularly in the biotechnological sphere, are from time to time allowing putative inventors to patent that which does not conform to traditional patent standards of novelty, nonobviousness, and useful function, not to mention morality. Some intellectual property regimes thus simultaneously and paradoxically grasp would-be inventors and the potential recipients of the benefits of this knowledge in a choking grip, blocking access to the raw materials of nature and research by making those materials subject to monopolistic control, and by including in the patent grant discoveries of natural phenomena and common knowledge, as well as true inventions.

Patent offices should be more circumspect in granting questionable patents, and judges should be more reluctant to uphold them. If outright bans on certain types of subject-matters and activities, or their patenting, are too daring for Congress, and might in certain cases even be regarded as unconstitutional, our legislators might at least make a start by broadening the “experimental use” exception and controlling more rigorously the patenting of therapeutic and diagnostic methods.